IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William W. Cimino	Examiner:	Laura A. Bouchelle
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19US01
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

FIRST SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.132 BY DR. MARK L. JEWELL, M.D.

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Mark L. Jewell, declare:

1. A declaration of mine (the previous declaration) was filed in the United States Patent and Trademark Office (USPTO) on February 22, 2011 in U.S. Patent Application Serial No. 10/600,118 (the present application) identified above. The previous declaration was submitted to provide objective evidence of nonobviousness for the invention claimed in the present application.

2. I am aware that the present application is currently rejected by the USPTO, and that the Examiner indicated in the latest office action that the previous declaration did not include enough information to establish that previously available devices did not satisfy the long felt need of delivering fluid rapidly and accurately during lipoplasty procedures.

3. I reaffirm the statements that I made in the previous declaration. This First Supplemental Declaration is being submitted to supplement the previous declaration, and in particular to provide facts regarding the deficiencies of prior devices used to deliver fluids in lipoplasty procedures.

4. As indicated in paragraphs 8 and 9 of the previous declaration, it is my understanding that the invention claimed in the present application is embodied in a precision fluid management system (PFMS) sold as part of Sound Surgical's VASER system, which I have used since its initial release.

5. I reiterate my statement from paragraph 12 of the previous declaration, namely that prior to the release of the VASER system incorporating the PFMS, I was not aware of any device that could deliver fluid with the necessary speed and accuracy for use in lipoplasty procedures.

6. In paragraphs 13-15 of the previous declaration, I summarized the two common systems and methods that were available for delivery of fluid in lipoplasty procedures, namely the use of prefilled syringes and the use of a pressure collar with intravenous (IV) bags. I also described some deficiencies of the two common systems, which made them inadequate for delivering fluid rapidly and accurately during lipoplasty procedures.

7. Exhibit A of this First Supplemental Declaration is an article, Gerald Bernstein, "Instrumentation for Liposuction," *Dermatologic Clinics*, vol. 17 (October 1999) p. 735, which describes the two systems that I mentioned in the previous declaration. Exhibit A describes some of the deficiencies in each of the systems and methods. Exhibit A does not disclose all of the deficiencies in the prior systems and methods, but does support my statements from the previous declaration indicating that the systems and methods previously available were deficient and did not adequately meet the need of rapidly and accurately delivering fluid in lipoplasty procedures.

8. On page 736, Exhibit A describes the use of syringes that are used to infiltrate tissue. As I stated in paragraph 14 of the previous declaration, syringes delivered fluid too slowly, which prolonged procedures. In paragraph 19 of the previous declaration, I also stated that prolonging a procedure could lead to surgeon fatigue. Exhibit A states with respect to syringes that "[t]hese devices are very effective although they also have the drawback of being slow. Also, frequent use of the refillable syringe over large areas may result in repetitive motion injury to the surgeon or nurse . . . ." *Exhibit A, page 736.* Exhibit A therefore supports my statements that use of refillable syringes did not provide adequate methods or systems for rapidly and accurately delivering fluids in lipoplasty procedures because of how slow the fluid was delivered and the possibility of surgeon fatigue or injury from repetitive motion.

9. I noted in paragraphs 14-17 of the previous declaration that systems that utilize pressure collars did not provide the necessary accuracy. Exhibit A further describes the use of pressure collars and IV bags for delivering fluid in a lipoplasty procedure. Exhibit A refers to the systems that use pressure collars and IV bags as "power IV infusors." *See Exhibit A, page 737.* Figure 2 in Exhibit A shows an example of one of the power IV infuser systems, which is similar to the device shown and described in Exhibit D of the previous declaration. As can be seen from Figure 2 in Exhibit A, the power IV infuser systems use line markings on the IV bag to measure the volume of fluid infiltrated into a patient, which is subject to inaccurate readings by a nurse or surgeon.

10. Exhibit A further describes other deficiencies of the power IV infusors including, "if the pressure is excessive, the tubing [connecting the IV bag to the infusion needle] may separate from the infusion needle and result in a spill. For this reason, IV infusion kits with luer-loks are less likely to become disconnected during use." *See Exhibit A, page 737.* Exhibit A recommends use of a handle with an on-off control in order to make the power infuser "less messy and more efficient." Spilling infusion fluid can create serious situations beyond being messy. Spilled fluid makes it difficult for a nurse or surgeon to determine the volume of fluid that has been infused into a patient. Exhibit A reinforces my statements that use of pressure collars and IV bags did not provide an adequate system and method to accurately deliver fluids in lipoplasty procedures.

11. Exhibit A further describes systems that use peristaltic pumps for delivering fluids in lipoplasty procedures. Figure 3 of Exhibit A illustrates some examples of systems that use peristaltic pumps. The systems do not provide features beyond line markings on an IV bag for determining the amount of fluid infiltrated into a patient. Line markings do not provide the necessary accuracy for determining the volume of fluid infiltrated into a patient, particularly when considering the safety implications of providing too much infiltration fluid.

12. In paragraphs 15 and 16 of the previous declaration, I stated that monitoring the amount of fluid infiltrated into a patient can have safety implications in lipoplasty procedures. Exhibit B of this First Supplemental Declaration is an article, Jeffrey A. Klein, "Anesthetic Formulations of Tumescent Solutions," *Dermatologic Clinics*, vol. 17 (October 1999) p. 751, which highlights the importance of monitoring the amount of fluid infiltrated into a patient during lipoplasty procedures.

13. As noted in Exhibit B, tumescent solutions used to infiltrate tissue during lipoplasty procedures using local anesthesia include lidocaine, which can be toxic. Exhibit B describes the importance of monitoring the amount of lidocaine that is provided to a patient. As indicated in Exhibit B, "[c]areless anesthesia records combined with a patient death may result in a prosecution for criminal negligence. There have been at least two such cases where the surgeon's notes did not accurately or unambiguously document the total dosage of lidocaine; in both cases the patients died after receiving general anesthesia plus tumescent local anesthesia, which was not well documented." *Exhibit B, p. 753.*

14. Accurately monitoring the amount of fluid infiltrated into a patient is critical. The power IV infusers and peristaltic pump systems, in use before the availability of Sound Surgical's PFMS, relied on line markings on an IV bag, are subject to inaccurate readings, which as indicated in Exhibit B can have fatal consequences.

15. I refer again to my statements in paragraphs 21 and 22 of the previous declaration. The PFMS provided a device that for the first time enabled aesthetic surgeons to deliver fluids

both quickly and accurately in lipoplasty procedures. The prior art devices and methods, described in Exhibit A of this First Supplemental Declaration did not satisfy the need for rapidly and accurately delivering fluid in lipoplasty procedures. Exhibit A supports my previous statements indicating the deficiencies in these devices.

16. I have also briefly reviewed the references that the USPTO has used to reject the claims in the present application during the course of examining the present application. None of the methods or devices described in the cited references satisfy the need that existed before the PFMS for rapidly and accurately delivering fluid in a lipoplasty procedure.

17. Some of the references previously used to reject the claims of the present application describe the use of intravenous (IV) systems that do not deliver fluids rapidly enough or with sufficient pressure for use in lipoplasty procedures (e.g., U.S. Patent No. 4,670,007 to Wheeldon et al.; U.S. Patent No. 5,910,135 to Hadzic et al.; and U.S. Patent No. 4,650,464 to Ruiz et al.). These methods and devices could not rapidly deliver fluid nor generate adequate pressure for infusing tissue as is necessary in lipoplasty procedures.

18. Other references used to reject the claims of the present application (e.g., U.S. Patent No. 4,650,462 to DeSatnick et al.; U.S. Patent No. 6,319,221 to Savage et al.; and U.S. Patent No. to 5,178,606 to Ognier et al.) describe the use of continuous flow systems that do not deliver a desired volume of fluid. Rather, these systems continuously provide fluid to an anatomical location. These methods and systems cannot be limited to delivering a desired volume of fluid, because the amount of fluid delivered will change depending on the needs of a procedure. Additional fluid may need to be delivered to keep a cavity extended e.g., a knee, or less fluid may be delivered if the pressure within the anatomical location becomes too high. These methods and devices therefore did not satisfy the need for rapidly and accurately delivering a desired volume of fluid in lipoplasty procedures.

19. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

Date: 12-22-2011

Mark L. Jewell, MD

Mark L. Jewell

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of: William W. Cimino	Group Art Unit: 3763
Application No.: 10/600,118	Examiner: Laura A. Bouchelle
Filed: June 20, 2003	Confirmation No.: 9143
Atty. File No.: 6613-19 (previously 40206.0019US01)	

For: PRECISION FLUID DELIVERY SYSTEM AND METHOD FOR SURGICAL PROCEDURES

FIRST SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.132 BY DR. MARK L. JEWELL, M.D.

EXHIBIT A

Article: Gerald Bernstein, "Instrumentation for Liposuction," Dermatologic Clinics, vol. 17 (October 1999)

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INSTRUMENTATION FOR LIPOSUCTION

Gerald Bernstein, MD

Since the introduction of liposuction into the United States in 1982, instrumentation for this procedure has undergone many significant changes. Great innovation and creativity have brought new and increasingly efficient instruments to the liposuction surgeon. Many of the improvements in both the safety and effectiveness of liposuction have been a result of the introduction of new instrumentation. Indeed one of the key factors in the development of liposuction as a viable procedure was the change in instrumentation from the sharp to the blunt cannula. Further developments, most notably the advent of the tumescent technique, developed by Dr. Jeffrey Klein in 1985, radically modified liposuction and further spurred the development of new innovative instrumentation to meet the demand.[13]

In addition to instrumentation directly used for liposuction, other instruments and equipment of a more ancillary or supportive nature are needed as well. This includes those necessary to increase patient safety, monitoring equipment, equipment to clean and sterilize the instruments, and products for postoperative care.

INSTRUMENTATION AND EQUIPMENT FOR INFUSING THE TUMESCENT SOLUTION

The tumescent solution, as originally developed by Dr. Jeffrey A. Klein, consisted of a solution of saline containing lidocaine (0.05% to 0.1%), adrenalin (1:1,000,000), and 12.5 mE of sodium bicarbonate to reduce stinging.[13, 14] This solution has been modified by some who add triamcinolone, 10 mg/L. In addition, many liposuction surgeons have replaced saline with Ringer's lactate, which changes the pH and obviates the need for sodium bicarbonate. It has been repeatedly shown that the infusion of this solution into the subcutaneous fatty layer will induce local anesthesia and vasoconstriction, which allow the procedure to be undertaken without additional general anesthesia and with greatly enhanced safety.[8, 13, 14, 18] Intraoperative and postoperative bleeding, which originally imposed serious limitations on the amount of fat that could be extracted, have been largely controlled by use of this solution. Limits to the amounts of lidocaine that can be safely infused have been discussed elsewhere. Although there is considerable discussion about the actual safe limits of lidocaine, 55 mg/kg, appears to be generally accepted as safe for most healthy patients.[20] Dr. Klein has suggested potential problems resulting from drug interactions with lidocaine and other substances, primarily selective seratonin reuptake inhibitors (SSRI) such as sertraline (Zoloft), which are metabolized by the liver, microsomal p450 3A4 (CYP3A4) enzyme system.[15] However, the actual potential for serious interactions with individuals who have

From the Department of Medicine, Division of Dermatology, University of Washington, School of Medicine, Seattle, Washington

normal liver function is yet to be demonstrated. The total volume of infused saline may also be a factor affecting the patient's safety and would depend on the patient's kidney, cardiac function, and blood pressure.

WARMING OF THE TUMESCENT SOLUTION

Many physicians will warm the tumescent solution prior to instillation into the subcutaneous space. Warmed saline probably produces less discomfort to the patient than the cool solution. In addition, because of the large volume of saline that is often infused, cool saline has the potential to lower the core temperature. This has been shown to increase the risk of morbid cardiac events and increase the potential for infection. Compromise of the clotting function and prolonged healing have been described as well.[6, 12, 22] Many physicians manage these problems by the use of warmed solutions. The solutions can be warmed either in a water bath made for this purpose or in microwave ovens. If the solution is to be warmed in a microwave oven, the physician must identify the exact duration that the IV bags can be safely placed in the microwave. As microwave ovens have different energy levels, an exposure that will safely warm an IV bag in one microwave oven may bring the temperature to an unacceptably high level in another. Whichever mechanism is used to warm the IV bags, it is critical that the temperature be carefully monitored to ensure that excessively hot tumescent solution is not being infused into the patient.

INSTRUMENTATION AND EQUIPMENT FOR INFUSION OF THE TUMESCENT SOLUTION

There are a variety of techniques and devices for effectively infusing the tumescent solution into the subcutaneous space.[9] Many of these devices are available commercially. The most simple technique is to use a 60-mL syringe attached to an infusion needle. The syringe is emptied individually and refilled by the nurse. Although simple and effective, this is a very inefficient technique. It can prolong the procedure and may lead to incomplete infiltration, especially when applied to a large surface area. It is, however, effective for liposuction touch-ups or treatment of very small areas. In addition, it can be used to harvest small amounts of fat for lipoinjection or for treatment of small lipomas.

A refinement of the simple syringe technique is the use of a syringe with a two-way stopcock. This will allow rapid refilling of the syringe from an IV bag. Several effective devices have been developed including many with spring-driven syringes to allow rapid refilling of the syringe after it has been emptied (Fig. 1). Many other reusable and resterilizible syringe-stopcock combinations have been developed that will more rapidly infuse solution. These devices are very effective although they also have the drawback of being slow. Also, frequent use of a refillable syringe over large areas may result in repetitive motion injury to the surgeon or nurse; however, these devices can be very useful for treatment of small areas such as the neck or knees,

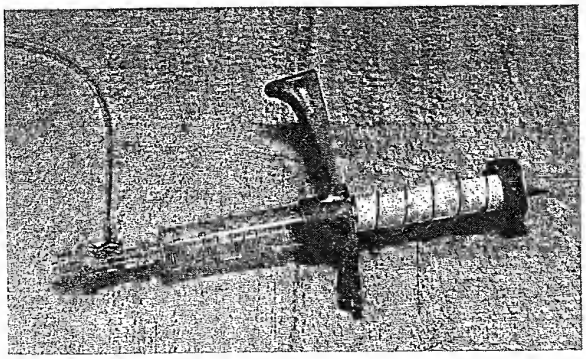

Figure 1. Spring-driven syringe with two-way stopcock (McGhan Medical Corp., Santa Barbara, CA). Plastic hose connects to IV bag containing tumescent solution. Allows rapid infusion of tumescent solution.

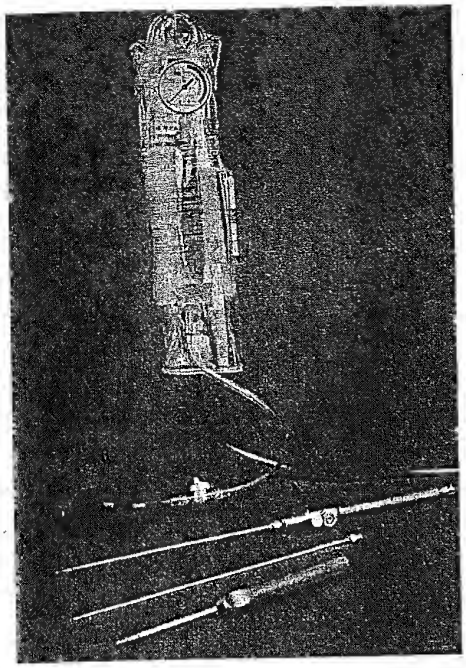

Figure 2. Intravenous (IV) power infusion device fits over the IV bag. Gauge indicates degree of pressure and mechanical switch on handle controls flow of tumescent solution.

touch-ups, or areas anesthetized to harvest fat for lipoinjection.

Power IV infusors (Byron Medical, Tucson, AZ) can be used to rapidly inject tumescent solution for liposuction patients (Fig. 2). This is an inexpensive way to rapidly infuse large volumes of tumescent solution. These devices usually cost less than $50.00. They fit over an IV bag and are inflated with a bulb pump similar to a sphygmomanometer. Indicators are usually provided to demonstrate an optimal and safe amount of pressure to infuse the solution. The IV bag is connected to the infusion needle with ordinary IV tubing; however, if the pressure is excessive, the tubing may separate from the infusion needle and result in a spill. For this reason, IV infusion kits with luer-loks are less likely to become disconnected during use. In addition, to more effectively use this approach, a handle with an on/off control should be present at the fingertips of the operator to easily turn the flow of solution on or off (see Fig. 2). Several such devices exist, such as the Hunstad Handle. This is a small handle that connects to the tubing on one side and the infusion needle on the other side. There is a simple thumb valve that is depressed to initiate the flow. This device will make the power infusor much less messy and more efficient.

The most efficient and effective way to infiltrate the tumescent solution is with a peristaltic pump (Fig. 3). Several varieties of variable-speed peristaltic pumps are available. Some use modified IV tubing whereas others use resterilizable silicon tubing. The tubing is connected directly to the IV bag, threaded through the power pump, and then connected directly to the infusing needle either with or without an intervening handle. Most pumps have variable speeds ranging from zero to over 400 to 600 mL/min. The most efficient pumps have two foot pedals so that one can be placed on each side of the operating table. In this manner, the operator can easily move from one side of the table to the other to access different parts of the body and make the infusion process more rapid. Otherwise, it is necessary to use either a hand switch, which is awkward and may compromise sterile technique, or a foot pedal, which has to be moved to each side of the table as the operator moves.

The limiting factor on the rate of flow of the tumescent solution is the size of the tubing and, most importantly, the size of the needle. A peristaltic infusion pump rated at 400 mL/min will only be able to deliver approximately 75 mL/min through an 18-gauge needle. A 15-gauge multiport needle, "garden-spray type", will accommodate up to 200 mL or more per minute. Also, the greater the diameter of the infusion tubing, the more rapidly the tumescent solution can be infused. Several infusion pumps have dual heads, allowing two operators to infuse the same patient simultaneously. This, however, must be done without the one operator interfering with the activities of the other. Some pumps actually have dual variable-speed pumps in the same device allowing for customization of the infusion process.

INFUSION NEEDLES

Tumescent solution can be instilled with a variety of needles. Klein recommends starting the infusion very slowly with a 25-gauge spinal needle (Jeffrey A. Klein, MD, personal communication, 1996). After a low level of anesthesia has been achieved, the size of the infusion needle is increased ultimately to 18 gauge. Other physicians will start with larger

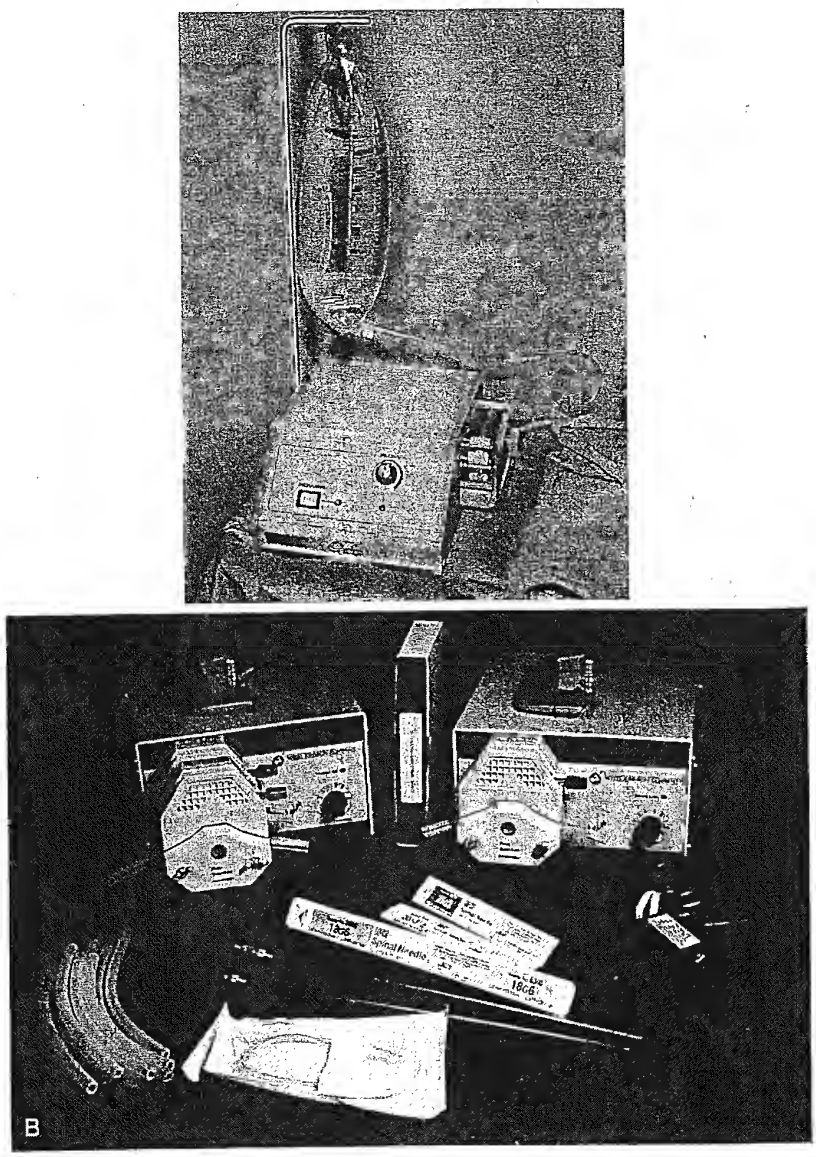

Figure 3. *A* and *B*, Various mechaical pumps for infusing tumescent solution. Most modern pumps have variable speeds (*A*, Tiemann/Bernsco Co., Hauppage, NY; *B*, Wells Johnson Co., Tucson, AZ).

needles, such as 18- or even 15-gauge multiport needles. The latter usually have 4 to 10 ports, which are situated on the last two inches of the cannula. The latter allow a much more rapid rate of infusion. Blunt tips tend to reduce the amount of discomfort and many patients will receive tumescent solution through a blunt-tipped multiport 15-gauge needle with little or no discomfort.

When patients experience pain, reducing the rate of infusion will often bring about immediate relief of the discomfort. After a small amount of solution has been instilled and anesthesia has been initiated, the infusion rate can be increased without further discomfort. Many operators will start by instilling deeply and then at a progressively higher level until the superficial plane has been anesthetized, therefore achieving firm tumescence.

LIPOSUCTION ASPIRATION EQUIPMENT

Liposuction is generally performed by two methods: the syringe method and the power pump method. The syringe method is enthusiastically supported by many liposuction surgeons.[7, 23] With the syringe method, the vacuum for liposuction is generated by withdrawing the plunger of a syringe while the cannula is in the place. Several locks exist that will hold the syringe out and maintain the negative pressure during the procedure (Fig. 4). When the syringe (usually a 60-mL syringe) is filled, it is withdrawn from the patient and handed to an assistant, who will empty the syringe while the physician continues the procedure with a second syringe. By trading off between the physician and the assistant, the procedure can move along quite rapidly. Most physicians who use the syringe method insist that their rate of aspiration is as rapid as aspiration conducted with a machine pump. A variety of cannulas have been made that fit over Toomey-type syringes. Cannulas also exist that will fit catheter syringes. The latter are somewhat less expensive than the Toomey. Also many cannulas have luer-loks and will fit on any standard syringe, which can then be used to aspirate the fat. In the latter instance, however, it is noted that the opening is relatively small. This will slow down the transfer process, as the fat often has to go from a larger-diameter cannula through the smaller diameter of the opening of the syringe.

Although there is diversity of opinion as to which is the preferable technique, syringe or machine-generated vacuum, most surgeons performing lipoinjection will harvest fat directly into a sterile syringe rather than with a pump. Although both syringe and mechanical aspiration methods achieve the same vacuum (i.e., 29 inches of Hg at sea level) the syringe is felt to be less traumatic to the fat cells. It is much easier, however, to maintain the fat in a sterile environment using the syringe technique. Also, a recent article has demonstrated viability of human lipocytes after the syringe method harvest.[12]

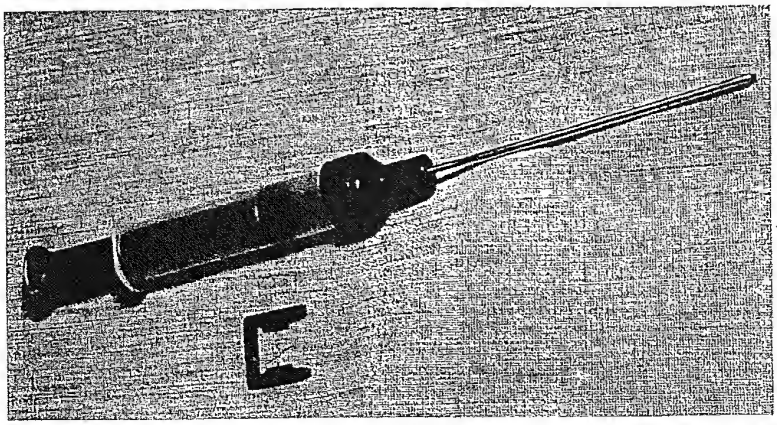

Figure 4. Liposuction cannula attached to a 60 mL *Toomey* type syringe. Vacuum is generated by withdrawing the plunger while the cannula is in the subcutaneous fatty space. A lock, which fits over the flange of the syringe, holds the plunger in place maintaining the negative pressure.

MECHANICAL ASPIRATION PUMPS

There are a variety of pumps made by several manufacturers of liposuction equipment (Fig. 5). Most pumps are either vane or piston-driven. The latter are more powerful but tend to be noisier. This may be a significant consideration when one is performing liposuction for several hours, as a high noise level can create tension and increase the level of stress during the procedure. Most machines will generate one atmosphere of negative pressure - 29 inches of Hg, relatively rapidly. Of course, at higher altitudes the level of negative pressure is reduced. In Colorado, for example, 23 to 24 inches of negative pressure is the maximum level of negative pressure that can be achieved. A recent article has suggested that more fat can be efficiently removed at 20 inches of Hg.[5] Also, many liposuction surgeons like to reduce the pressure while doing liposuction of the face, neck, and submental area. Some of the higher-quality machines have the capability of varying the pressure.

PREOPERATIVE AND INTRAOPERATIVE ULTRASONIC LIPOSUCTION

Ultrasound has been used in liposuction both internally and externally. Internal, ultrasonic-assisted liposuction uses cannulas that oscillate at approximately 15,000 to 30,000 Hz. The lipocytes are imploded, which liquefies the fat. This modality is adequately discussed elsewhere (see the article by Lawrence and Coleman in this issue) and will not be reviewed in this article.[2, 16, 24, 25]

The application of external ultrasound has been advocated as well. This technique uses ultrasound in the 1 MHz frequency at 2 to 3 W/CM^2 applied to the skin overlying the areas to be treated, after instilling the tumescent solution but before performing the actual li-

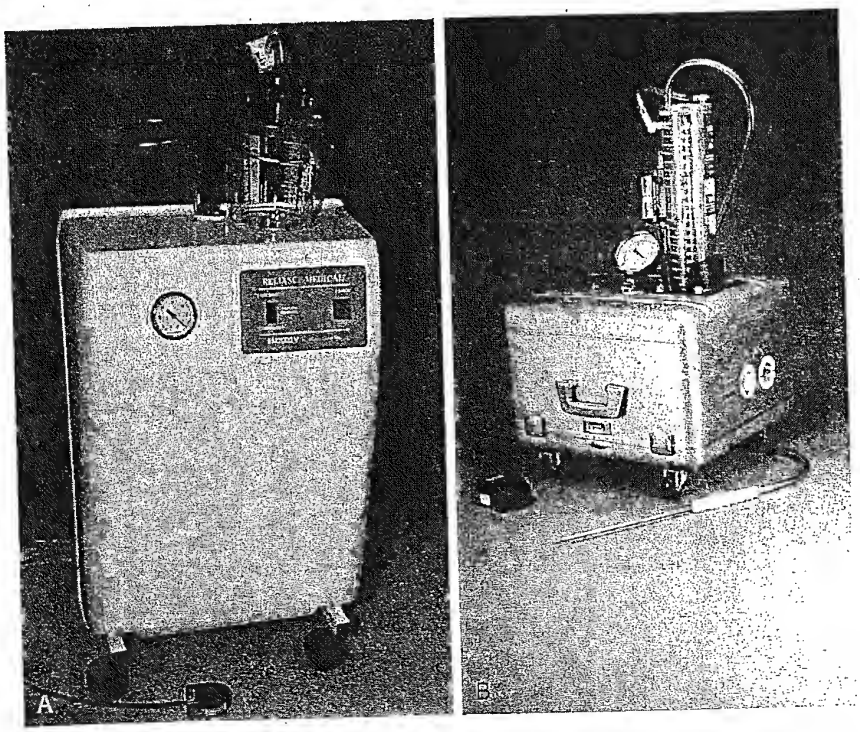

Figure 5. Examples of electric-powered liposuction aspirators. *A*, This respirator features a rigid plastic collection canister (Tiemann/Bernsco Co., Hauppage, NY), which is discarded after each use. There is an internal valve that prevents overflow of fat and fluid into the machine. It is relatively inexpensive. The collection canister featured in *B* has a soft plastic bag placed in an external rigid canister (Byron Medical, Tucson, AZ).

posuction surgery. In this instance, the actual aspiration is performed in the conventional fashion with hollow cannulas and an aspirating machine. This subject is also discussed in the article by Lawrence and Coleman and will not be further reviewed in this article.[3, 10]

COLLECTION DEVICES AND FILTERS

Modern collection devices are either made of glass or plastic materials. The graduated glass collection devices are becoming relatively scarce and are often hard to replace when broken. Their fragility somewhat limits their usefulness and, in fact, they are probably much less efficient because they have to be emptied and cleaned after each use. This is less of a problem in small-volume cases, where one glass jar will be adequate for an entire case, than in large volume cases, where the collection jars have to be frequently emptied throughout the course of a procedure.

Plastic collection devices are either rigid or soft. The rigid canisters can be 1-, 2-, or even 3-L graduated containers that are made of clear plastic (see Fig. 5*A*). This allows easy estimation of the aspirated volumes of fat and fluid. They generally have multiple ports, allowing various sizes of tubing to be connected. Some of the better-quality products have an internal shut-off device, which prevents overflow. If overflowing liquids are aspirated into the machinery of the pump, the aspirator will be ruined and require servicing. Most manufacturers will not warranty aspirator pumps that have been damaged by fluid. The rigid plastic containers will occasionally crack, allowing in air, lowering vacuum pressure and requiring replacement.

There is some variation in the soft collection devices or bags. To be effective they are set in a rigid, clear-plastic, graduated outer container (see Fig. 5B). In order to keep the collection bags expanded (and therefore able to receive the aspirated fat), some of the vacuum must be diverted into the space between the bag and the outer canister. The weakness of this collection system is that if air leaks develop in the rigid column, the internal liner will collapse and the liposuction procedure must stop. Unfortunately cracks do occur, especially around the metal or plastic connectors. If a standby rigid outer column is not available, one would have to find some way to seal the leak or else the operation will have to be halted.

There are two types of aspiration hoses: the stiff clear-plastic hoses and the soft, somewhat thinner hoses. The rigidity of the clear-plastic hoses make them clumsy and adds weight to the procedure. Many physicians prefer the thinner, softer hoses, which are equally efficient and effective in moving the fat from the cannula into the collection system. Because they are soft they cause less drag on the operator's hand. The weight and stiffness of the thicker clear-plastic hoses will often require a surgeon to have a standby nurse doing nothing more than supporting the hose during the procedure. The hoses used in liposuction cannot be resterilized. They become stiff, opaque, and fragile in an autoclave. Therefore, they must be discarded after each use.

CANNULAS

Liposuction sparked the development of many new cannulas, which were invented both by liposuction surgeons and innovative manufacturers. Originally many curved forms were available; however, most modern liposuction cannulas are now straight. The cannulas themselves are made of stainless steel, but the handles can be either stainless steel, aluminum, deldrin, or even brass. The latter are quite heavy. When liposuction first appeared in the United States, standard cannulas were up to 10 mm in diameter or even larger. Fifteen millimeter cannulas were used as well. Now, cannulas tend to be small; the more common cannulas used by dermatologic and other surgeons are 2- to 4-mm in diameter. Dr. Klein developed cannulas that were measured in gauge rather than millimeters. The gauge equivalents are indicated in Table 1.

The chief factors involved in selecting a cannula are the tip configuration, the diameter, and the length and shape of the handle. The handles should be of a size that is comfortable for the operator. Because liposuction cannulas must be gripped continuously for

Table 1. GAUGE-MILLIMETER EQUIVALENTS

Gauge		Equivalent
8 gauge	=	4.2 mm
10 gauge	=	3.4 mm
12 gauge	=	2.8 mm
14 gauge	=	2.2 mm

many hours at a time, an ill-fitted handle can result in repetitive motion injury. Therefore, one should carefully select cannulas that comfortably fit the hand.

The length of the cannula itself should be adequate to reach all parts of the treated area. Longer cannulas may be somewhat less controllable than shorter cannulas. The use of very long cannulas, especially in the hands of inexperienced surgeons, can sometimes lead to the cannula being accidentally misdirected during the procedure. This is especially true when encountering areas that are more fibrotic than surrounding areas, as in old surgical scars and in areas that are being treated after prior liposuction. The use of the shortest possible cannula to perform the job is encouraged, especially in the hands of inexperienced surgeons or when using very thin cannulas.

The handles of virtually all liposuction cannulas have a depression or dimple where the thumb should be placed (Fig. 6). This dimple indicates the up position and, when one's thumb is place, the openings can be expected to be exactly 180° away and therefore always pointing in the "downward" [correct] direction. The dominant direction of the ports of most cannulas is downward. However, some cannulas, such as the radial triport, have two openings that are angled 60° from the up position. Therefore, there is potential for trauma to the dermis and dermal blood vessels if these cannulas are used in a very superficial plane. This may be a theoretical consideration as no significant ill effects to the dermis have been specifically attributed to the use of radial triport or similar cannulas. Some surgeons prefer a small hole in the depression of the handle, which allows them to control the vacuum with their thumb.

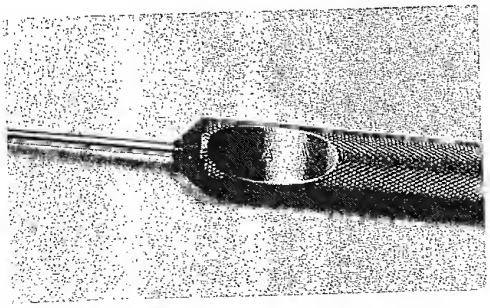

Figure 6. Cannula with typical dimple in the handle for placement of the thumb. This depression indicates the up position for the cannula.

The tips of cannulas generally come in one of three shapes: bullet, spatula, or rounded (Fig. 7). For most liposuction the use of bullet and spatula cannulas is encouraged because of the reduced friction and therefore greater ease of use.

The actual number, pattern, and size of the openings or ports in the cannulas greatly determine their relative aggressiveness. Although many tip configurations have been developed since liposuction was first introduced, there are a dozen or so cannulas that have survived to the present because of their usefulness and effectiveness. I categorize cannula port configurations as being conservative, moderately aggressive, and very aggressive. Note that there is no uniformity in the size or shapes of the ports of cannulas made by different manufacturers. Therefore, similar cannulas made by different manufacturers will differ in the degree of aggressiveness (Fig. 8). Also, cannulas are now available that are coated with polytetrafluoroethylene, which can reduce resistance during liposuction (Fig. 9). This is especially useful when operating in fibrous areas such as love handles and gynecomastia.

Conservative cannulas will have one or two openings. The openings are usually somewhat set back from the actual tip. The ports on the conservative cannulas may be somewhat small. Single- or dual-port standard or spatula cannulas are examples of conservative cannulas (see Fig. 8).

Moderately aggressive cannulas include some larger dual-port cannulas such as the Texas cannula. Cannulas with ports at the very tip tend to collect fibrous tissue during the procedure. They have to be cleared regularly throughout the procedure. Examples include dual-port standard and spatula cannulas with larger openings, two-port Eliminator openings, Texas cannula, the Fournier, and the two-port standard cannula (see Fig. 8).

More aggressive cannulas include the Cobra and Pinto cannulas, which have two openings at the tip and one below. Others, such as the Becker and Eliminator cannulas, are also considered rapid harvesters of fat (see Fig. 7).

Most liposuction surgeons will settle on a relatively small number of cannulas with which they have experience and are comfortable. One is encouraged to have a number of "favorite" cannulas in various diameters and length. Occasionally cannulas become contaminated during surgery. Not having another sterile cannula on hand will require the

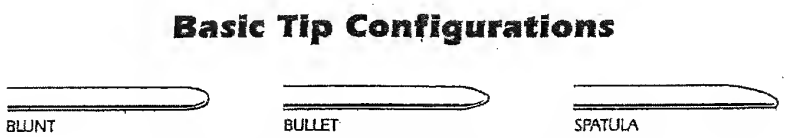

Figure 7. Examples of basic liposuction cannula tip configurations.

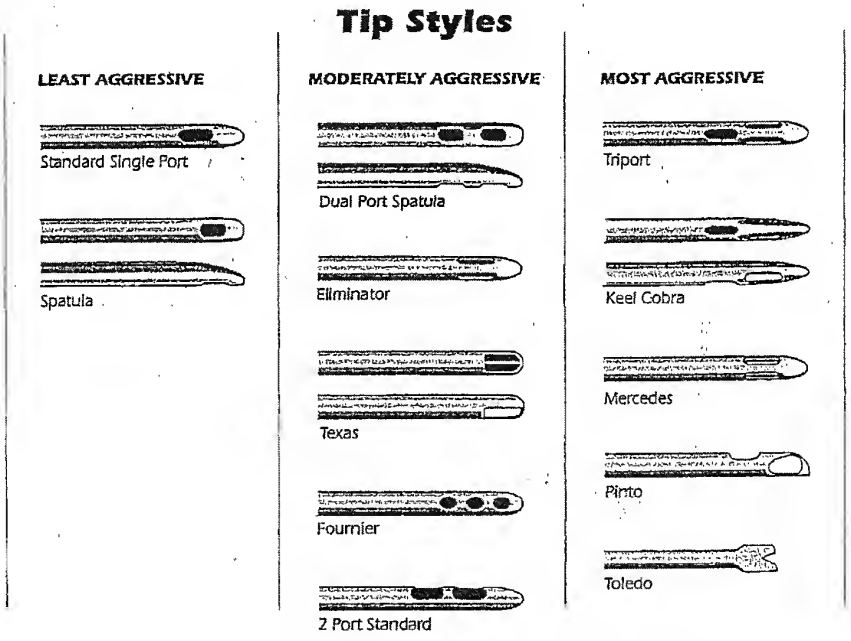

Figure 8. Comparison of identical tri-port cannulas made by different manufacturers. Note the difference in the size of the ports. The larger one is expected to be a more aggressive cannula than the smaller.

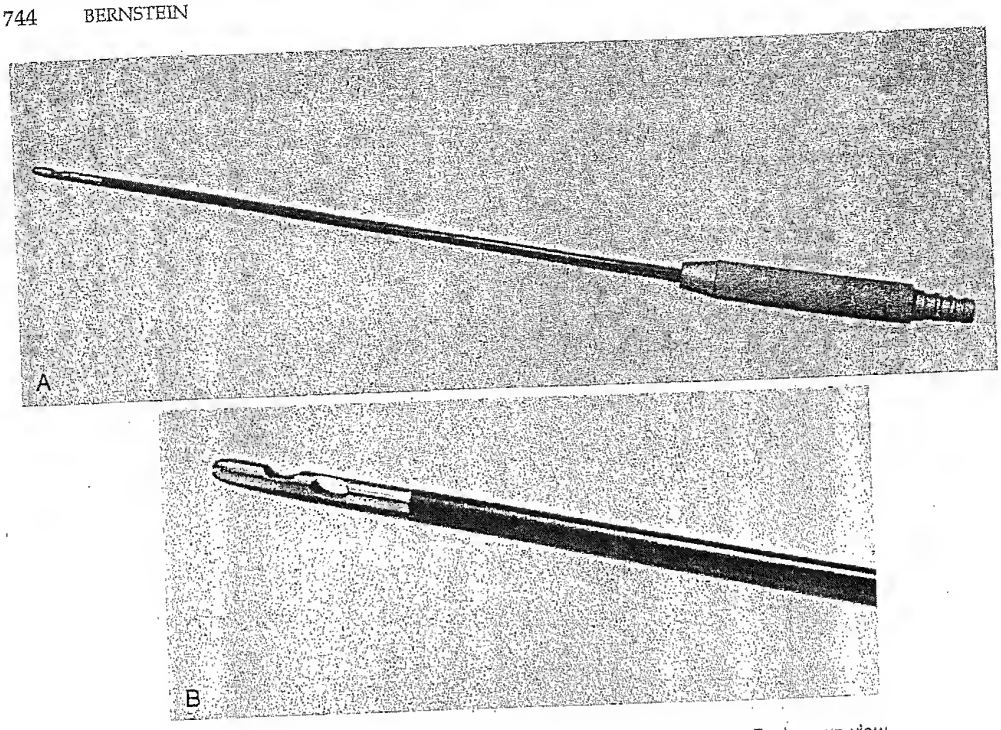

Figure 9. *A*, Example of PTFE cannula of a tri-port (Eliminator) type design. *B*, close-up view.

procedure to cease while the cannula is being cleaned and resterilized.

CLEANING CANNULAS

Of course cannulas used for liposuction must be adequately cleaned and sterilized after each use. Adequate cleaning includes irrigation of the cannula with a syringe or other pressure device and use of a brush to remove particulate matter from the cannula. To effectively remove all debris, however, the use of an ultrasonic cleaner is urged. Cleaners are available in adequate lengths to accommodate most liposuction cannulas. After the cannulas have been removed from the ultrasonic cleaner they are again rinsed, dried, and sterilized in an autoclave. A large autoclave will be necessary to accommodate the length of liposuction cannulas.

THE STERILE OPERATING THEATER

Ideally, the operating room for liposuction should be large enough for the operating table to be placed in the center of the room. The surgeon can then approach the patient from all directions. As most surgeons are not ambidextrous, it is important to be able to approach the patient from the right or left side to adequately access all fatty deposits. A table with an electric motor or pneumatic pump will allow the surgeon to change the level of the table during the procedure. This will be more convenient and comfortable for the surgeon and there will be less strain to the back, shoulders, and arms. Comfortable access to all fatty deposits can be expected to provide a better and even cosmetic result. In addition, there should be adequate ventilation and facilities for heat because patients often become cold during the course of the procedure. There should also be adequate room for the machinery, equipment, and supporting Mayo stands, etc., which are used during the procedure while still allowing ample room for the surgeon and staff to perform their tasks.

Liposuction has been demonstrated to be an extremely safe procedure.[9] Nonetheless, the maintenance of a sterile environment is elementary. Sterile gowns, adequately sterile

draped tables, instrument trays, and other equipment may be necessary to maintain an aseptic operating field. Several sterile "basic" packs are available at low cost and can cover all operating and instrument surfaces with waterproof or water-resistant disposable fabrics (Fig. 10). These are available with sterile gowns for the physician as well. Not only do they transform the operatory into a credible operating room, they also go far to ensuring a safer, sterile environment for the patient and a more favorable outcome.

MONITORING

It is considered appropriate by many surgeons to monitor all but the simplest liposuction procedures. Monitoring usually includes blood pressure, pulse, oxygen saturation, and echocardiogram. Some surgeons measure body temperature as well. Many devices are available to perform these monitoring functions. The monitors can either be separate or combined in a single computerized monitor (Fig. 11). The latter are more efficient and save

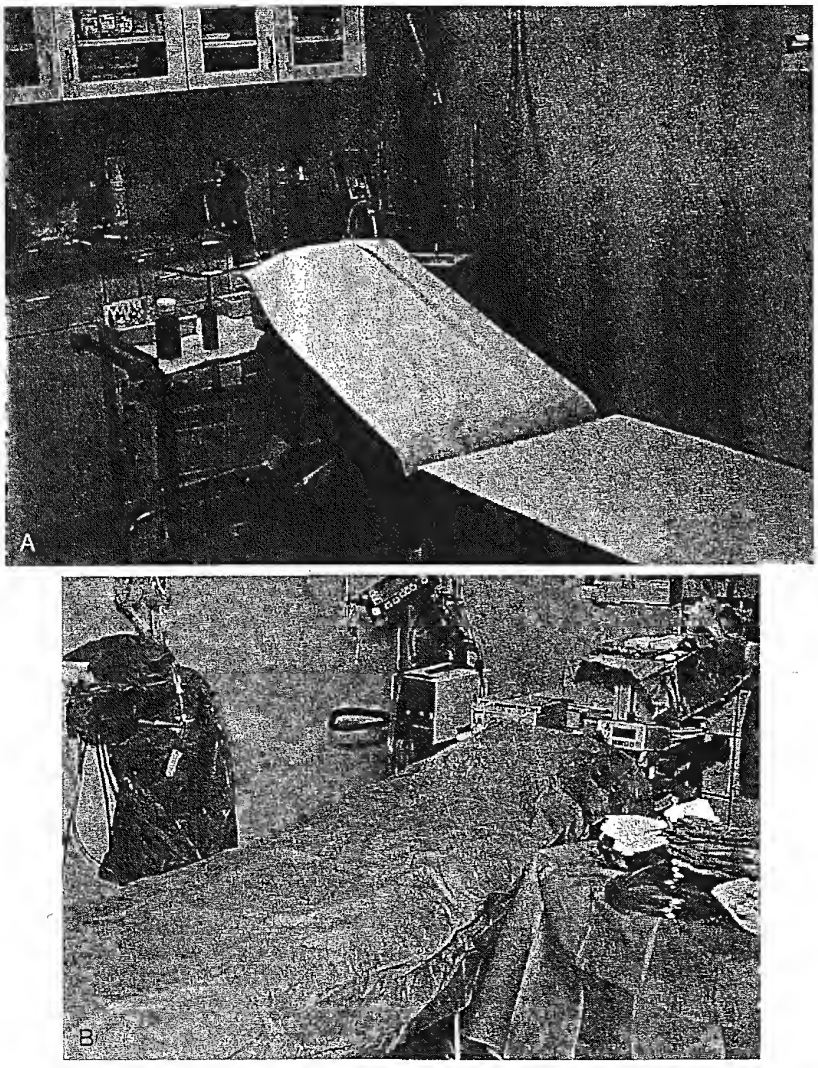

Figure 10. *A*, Operating table is placed in center of large operating room. Allows easy access to patient from all sides. *B*, Operating table covered with sterile waterproof cover. All operating surfaces covered with sterile drapes.

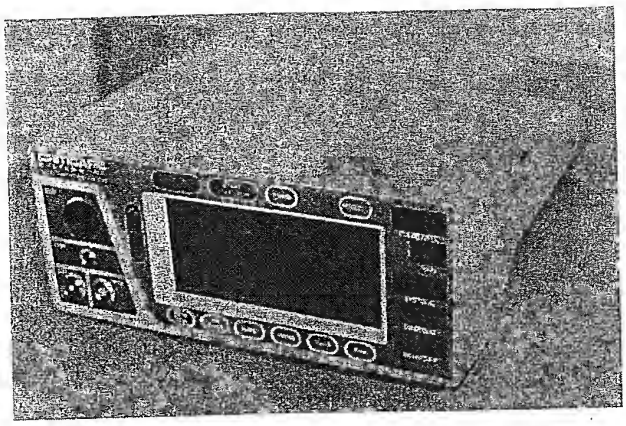

Figure 11. Multiple monitor appropriate for liposuction measures blood pressure, pulse, oxygen saturation, and echocardiogram. Body temperature monitor available as well.

space. Although many surgeons do not feel the need to regularly monitor healthy low-risk patients, the capability to do so should be available in case of an emergency.

ANCILLARY EQUIPMENT

In addition to the previously mentioned instruments and equipment, there are a variety of other instruments that should be considered to be useful and important in liposuction surgery. Because of the length of the procedure and the exposure of large surface areas of patient's skin, many surgeons prefer to have warming devices for their patients. As mentioned earlier, there is evidence that prolonged chilling stresses the heart and raises the risk of infection.[6, 17] Impaired clotting function and prolonged healing from mild hypothermia have been reported as well.[22] The use of electric heating pads is discouraged because of the possibility of burns or electrical shorts. The POPP* bed warmer circulates warm distilled

*The POPP bed warmer was named after Dr. Jeffrey Popp, Omaha, Nebraska, who discovered this unit and recommended it's use. It is manufactured by Gaymar Co., Buffalo, NY.

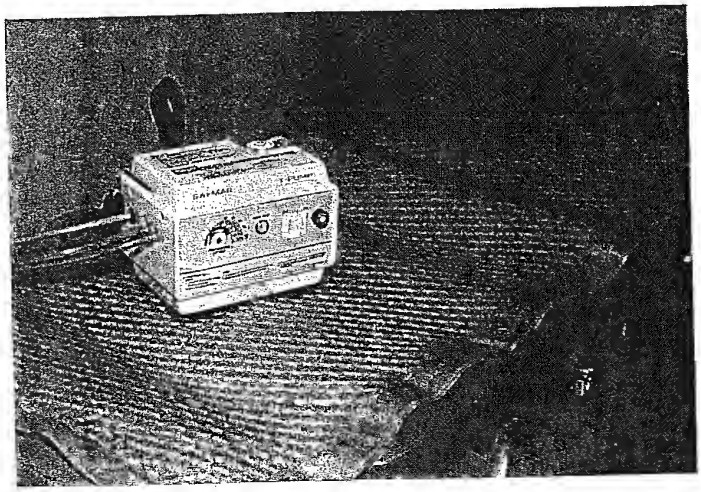

Figure 12. Bed warmer circulates warm water through rubberized blanket placed beneath the patient to maintain patient comfort and avoid lowering of body temperature.

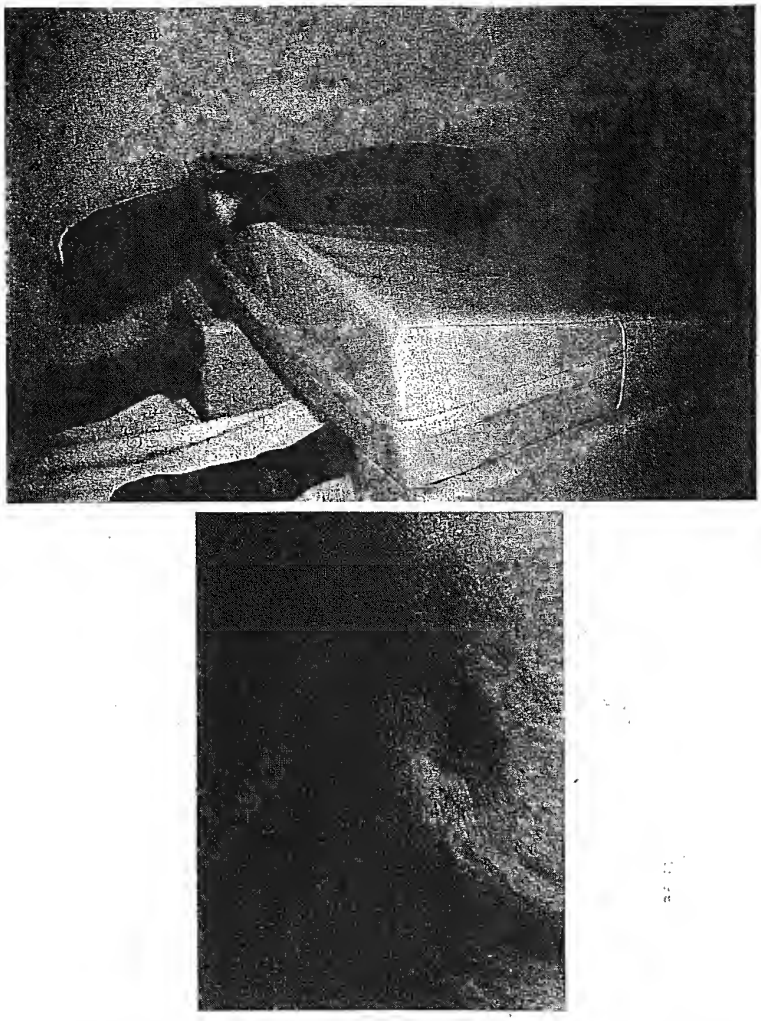

Figure 13. *A,* View of patient's leg on wedge demonstrating position during liposuction. *B,* Using this device, one can reduce the likelihood of forming a depression in the posttrochanteric space, as shown here.

water through a rubberized mat placed beneath the patient (Fig. 12). As the heating device is separated from the patient, there is no danger of electrical accidents. In addition, the upper limit to the temperature is 105°F, so there is no possibility of burning the patient. Most patients find this extremely comfortable, especially during long procedures. The heating pad is appropriately placed beneath the sterile waterproof table covers.

Another device, the leg wedge, is used to elevate the thigh during liposuction of the trochanteric or saddlebag area. When properly used, the foot extends beyond the wedge and is pointed downward, rotating the trochanter forward. This allows liposuction in an area of posttrochanteric depression that, if over-resected, will create a permanent indentation. The device usually has a smaller pad on which to rest the upper knee when performing liposuction of the medial thighs with the patient in the lateral decubitus position (Fig. 13).

POSTOPERATIVE GARMENTS

There are a variety of postoperative garments that are used for liposuction patients.

As many surgeons want their patients to wear these garments continuously for at least several days, appropriate openings are provided so that they may go to the bathroom without removing the garments. The garments are generally made with the zippers and snaps on the outside to avoid discomfort to the patient. Many styles of garments are available, which vary slightly in size, shape and degree of compressiveness. They are worn for as short a period as a few days to as long as a month or more. Some patients prefer to wear these garments even longer because they feel comfortable.

Some liposuction surgeons prefer the use of a compressive tape, which is applied in a herring bone or criss-cross fashion, either with or without the supplementary compressive garments. This too is a matter of professional preference. There is no evidence that this practice provides a better long-term cosmetic result.

Liposuction of the calves and ankles often results in long-lasting edema.[8, 19–21] In order to control postoperative edema, patients are advised to use fitted compressive hose, 30 to 40 mm Hg, which they will wear for prolonged periods. Although some surgeons recommend that these compressive stockings be worn continuously, others recommend use of 30 to 40 mm Hg during the day, when the patient is ambulatory, and to use only 18 mm Hg hose at night when the legs are somewhat elevated.[19, 21]

ULTRASOUND

Postoperative therapeutic ultrasound, usually at a frequency of 1 mH, has been used effectively to reduce edema, induration, and discomfort (Fig. 14). Many patients note significant improvement when this is applied during the early postoperative phase. Some therapists recommend that ultrasound not be used until 2 weeks postoperatively whereas others encourage its use in the very early postoperative inflammatory stage.[4] It is important that nurses and assistants applying the ultrasound be acquainted with the proper use and especially the risks of ultrasound. Many surgeons find that ultrasound is an in-

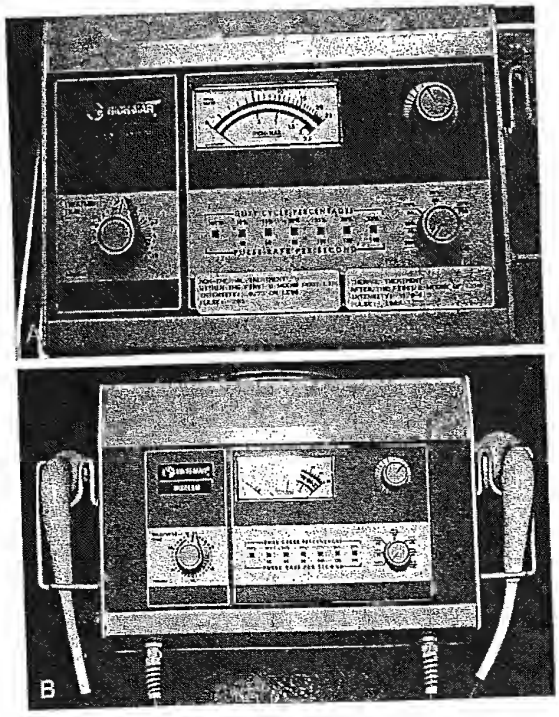

Figure 14. *A*, One- and *B*, three-watt ultrasonic generators that can be used for preoperative or postoperative liposuction.

valuable aid to the postoperative care of their patients.[1, 11]

CONCLUSION

Modern liposuction has been proven over the past two decades to be an extremely safe and effective technique for the removal of unwanted fatty deposits. Attention to proper surgical techniques plus the use of proven safe and effective instruments and equipment, will help ensure that the physician offers and that the patient receives the finest in surgical treatment. It is important that the equipment be frequently examined and well-maintained. We can look forward to further enhancements in instrumentation for this remarkable procedure in the coming decades.

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